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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tebuthiuron

HED Project No.: 9-1617
TOX Chem No.: 366AA

FROM: Ray Landolt 10/18/89
Review Section I
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THRU: Mike Ioannou, Section Head M Ioannou 10/19/89
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Toxicology Branch II - Herbicide, Fungicide, and
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and

Marcia van Gemert, Branch Chief M van Gemert 10/27/89
Toxicology Branch II - Herbicide, Fungicide, and
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Registrant: Elanco Products Company, Letter of June 5, 1989

Action Requested

In response to the deficiencies cited in the review by D. Ritter, November 4, 1988 (copy attached) of the rabbit

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teratology study (MRID No. 000206-44) Elanco has submitted the following data (MRID No. 411224-01):

1. The purity and composition of the test material used in the rabbit teratology study conducted in 1975 and the purity and composition of the currently registered technical formulation of tebuthiuron.

2. A description of the procedure used to inseminate the female rabbits tested in this study.

Results

1. The rabbit teratology study (MRID No. 00020644) was conducted with tebuthiuron (EL-103, Compound 75503) of Lot No. B30-23-149 and a purity of 96.5 percent. At the time this study was conducted (Study Date: April 1975), a detailed analysis of the impurities was not performed. This lot of tebuthiuron and subsequent lots (up to 1985) were produced by the [redacted] Subsequent lots of tebuthiuron produced during this period were characterized for impurities. [redacted] The current production of tebuthiuron used for toxicity testing (Lot No. 729AS7) has a purity of 99.08 percent. This results in an approximate 2.6 percent increased concentration of tebuthiuron greater than that administered in the rabbit teratology study. Considering the marginal systemic effects observed in the rabbit teratology at the 25 mg/kg level (reduced fetal body weight), an increase of 2.6 percent in the concentration of tebuthiuron is not likely to change the systemic NOEL 10 mg/kg reported in this study.

2. The description of the insemination procedure is adequate.

Conclusion

1. Classification of Data - Minimum

2. Developmental NOEL > 25 mg/kg (HDT)
   Maternal NOEL 25 mg/kg
   Fetotoxic NOEL 10 mg/kg
   Fetotoxic LEL 25 mg/kg with a reduced fetal body weight reported at the time of post-mortem examination.